



SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Dalene T. Binkley
Telephone: (574) 267-6639

Proprietary Name: HA Modular Reach™ Proximal Porous and HA Modular Reach™ Collared Proximal Porous Femoral Stems

Common Name: Prosthetic Hip Joint – Hydroxyapatite (HA) Coated Porous Femoral Stem

Classification: hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Device Classification: Class II

Legally Marketed Device to which Substantial Equivalence is Claimed: Modular Reach™ Hip- 510(k) K994038.

Device Description: The HA Modular Reach™ Proximal Porous and HA Modular Reach™ Collared Proximal Porous Femoral Stems are the same as their predicate, except for a modified profile on two of the sizes and the addition of Hydroxyapatite Coating.

Indications for Use: The indications for the HA Modular Reach™ Proximal Porous and HA Modular Reach™ Collared Proximal Porous Femoral Stems are for) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Correction of functional deformity; 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and 5) Revision procedures where other treatments or devices have failed.

Summary of Technologies: The HA Modular Reach™ Proximal Porous and HA Modular Reach™ Collared Proximal Porous Femoral Stems- the materials, design, sizing, and indications are similar or identical to the predicate devices.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

060046

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

Non-Clinical Testing: Mechanical Testing with an Engineering Justification determined that the HA Modular Reach™ Proximal Porous and HA Modular Reach™ Collared Proximal Porous Femoral Stems presented no new risks and were, therefore, substantially equivalent to the predicate device.

Clinical Testing: No clinical testing was provided as a basis for substantial equivalence.



AUG 16 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dalene T. Binkley
Regulatory Affairs Specialist
Biomet Orthopedics, Inc.
P.O. box 587
Warsaw, Indiana 46581-0587

Re: K022463

Trade/Device Name: HA Modular Reach™ Proximal Porous and HA Modular Reach™
Collared Proximal Porous Femoral Stems

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated
Uncemented Prosthesis

Regulatory Class: Class II

Product Code: LPH

Dated: July 15, 2002

Received: July 26, 2002

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

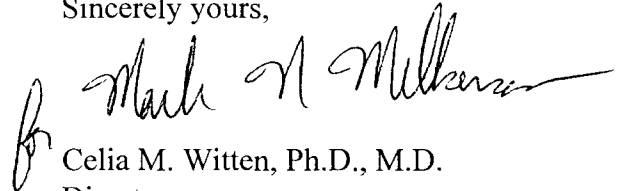
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K022463

DEVICE NAME: HA Modular Reach™ Proximal Porous and HA Modular Reach™ Collared Proximal Porous Femoral Stems

INDICATIONS FOR USE:

The indications for the HA Modular Reach™ Proximal Porous and HA Modular Reach™ Collared Proximal Porous Femoral Stems are for) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Correction of functional deformity; 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and 5) Revision procedures where other treatments or devices have failed.

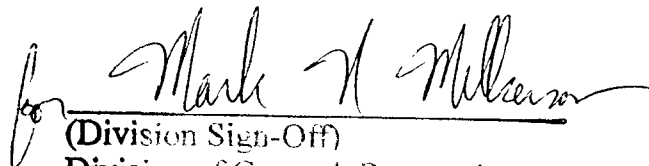
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use No
(Optional Format 1-2-96)


(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K022463

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